

Notice of Allowability	Application No.	Applicant(s)	
	10/560,513	GARCON ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/15/10.
2. ☒ The allowed claim(s) is/are 13 and 63.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>2/15/10</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Jennifer E. Graser/
 Primary Examiner, Art Unit 1645

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance:

The prior art does not teach or suggest immunogenic compositions comprising a capsular polyribosylribitol phosphate (PRP) polysaccharide of *Haemophilus influenzae* B and a polyanionic polymer, wherein the polyanionic polymer is poly-L-glutamic acid (PLG).

PLGA or DL-PLG microspheres (poly(lactide-co-glycolide)) are not the same as the recited PLG (poly-L-glutamic acid). PLGA is not a polyanionic polymer. The instant application provides unexpected results that PLG (poly-L-glutamate) avoids flocculation induced by PRP and that the presence of PLG in Hib formulations reduces immune interference between PRP and Ifanrix-Penta combinations (vaccine comprising multiple antigens). The specification teaches that Applicants have discovered that adding PLG to a vaccine comprising PRP and aluminum hydroxide allows for the PLG to compete with PRP thereby protecting it from any aluminum hydroxide present in the vaccine, e.g., by reducing the amount or rate of binding of PRP to adjuvant and/or the extent or rate of flocculation, yet surprisingly does not cause antigens already absorbed to aluminum hydroxide to become significantly desorbed.

US Patent No. 6,339,062 mentions PRP and poly-L-glutamic acid in the specification. However, PRP in this application is in reference to Platelet-rich-plasma (PRP), not capsular polyribosylribitol polysaccharide of *H. influenzae* B.

PLGA and PLA are not anionic polymers nor are they readily water soluble. They are not the same as PLG. Applicants cited (1) pages 1529-1530 from the Aldrich Handbook of fine chemicals 2003-2004 showing that these chemicals do not have anionic repeating units, and (2) a current MSDS for 50:50 poly(DL-lactide-co-glycolide) polymers from Birmingham Polymers, www.birminghampolymers.com, www.absorbables.com/documents/DL-PLGMSDS.pdf, the company from which Gupta et al. obtained their microspheres, Gupta et al. p. 59).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

2/19/10